

UniCoV Information Sheet

(version 2.0 dated 9 June 2021)

We invite you to join the UniCoV COVID-19 research study. This form gives information about the research study so it is important to read it carefully.

Why is this research being done? Our research project is to develop a surveillance system for SARS-Cov-2 infection based on rapid testing methods. Rapid testing is an additional tool that can quickly identify those that are infectious. If a rapid test is done at least two times each week, it increases the sensitivity of the test i.e. the likelihood of the test being truly positive. Any person with a positive test will have this confirmed by the HSE PCR testing system.

The return to on-campus activity is constrained by risks to university staff arising from face-to-face education of large cohorts of unvaccinated students. The development of a surveillance system for third-level institutes would aid in the return to on-campus learning by providing a safer environment for students and staff and increasing their confidence and assurance that this is a low-risk environment in which to work and study.

What is COVID-19 (coronavirus)? COVID-19, caused by SARS-CoV2 virus, is a new infectious disease. Most people who get infected have either no symptoms or have a mild illness. However, it can cause a more severe illness predominantly affecting the lungs and in some cases can cause death, particularly in people who are older or have other underlying illnesses.

Who is doing this study and who is sponsoring and funding it? This study is led by investigators across each of the participating university sites – National University of Ireland Galway (NUIG), Trinity College Dublin (TCD), University College Dublin (UCD), and University College Cork (UCC). The research project is co-funded by the Science Foundation Ireland (SFI) Strategic Partnership Programme and the participating HEIs.

How will I be recruited to this study? Participants will be asked to access a web enabled application e.g. UniCoV website or app. (A UniCoV app is being developed and you will be able to download this app from NUIG Power apps). Your data from the web enhanced application is stored in a secured Sharepoint file within NUI Galway Microsoft architecture.

What type of tests will be used? We will ask each volunteer amongst the universities' students and staff to perform a self-administered nasal swab and provide a sample of saliva. The nasal swab will be analysed by a lateral flow device which is similar to a pregnancy test.. An Instructional video on how to do this will be provided to each participant via the UniCoV application. The saliva test will be dropped off at a designated location and processed in the laboratory.

Who can provide nasal and saliva samples to this study? Research volunteers that are students or staff of one of the participating HEIs can provide samples to this research project. Samples will not be accepted from individuals who have been diagnosed with COVID-19 within the previous 6 months of study onset and certain vulnerable groups.

What happens next if I agree to join this study? If you decide to join as a volunteer, you will be asked to access a web enabled application and read and agree to a consent agreement. Next, we will indicate to you how to donate your sample(s). We may ask you to donate repeat biological samples, at regular intervals (e.g. twice per week).

Will my details be kept confidential? Yes. Best ethical and legal practice will be followed to ensure that all your information will be handled in confidence.

Your samples will be labelled with a barcode linked to a unique sample study number. Access to your personal details will only be available to necessary clinical researchers on this project in the Student Health Unit. This will be accessed for the purposes of clinical assessments relating to symptoms of COVID-19 or referring you for a HSE COVID-19 test. We will also request that your HSE test result be shared with the study.

You will not be identified personally in any report or publication arising from the analysis of your samples and/or data. Your data will be stored securely within the NUI Galway data security structure via Microsoft. Anonymised aggregated metrics will be visible on the UniCoV website dashboard for example positivity rate, incidence rate etc.

Can I know the results obtained from my study samples? In the event that your sample yields a positive indication for SARS-CoV-2, you will be asked to contact the Student Health Centre and you will be offered an appointment for an official SARSCoV-2 test conducted in an official clinical HSE testing centre (where this is available under the latest Guidelines) and advised to follow the latest HSE Guidelines. We will also ask that you agree to the result of your HSE test being made available to the study.

What if I no longer want to be in the research study? You are free to withdraw from participation in the research study at any time without giving a reason. If you choose to withdraw, you can either (1) ask us to stop further contact with you, but allow us to continue accessing your existing samples for the COVID-19 research study, or (2) you can ask us to also stop further use of your data and destroy your remaining samples. Any research already done with your data and samples cannot be undone.

Who do I contact for further information? If you would like more information or have any queries, please see the UniCoV website which contains useful information and frequently asked questions.

Research Study Leaders

NUIG lead:

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Figure 1 Flow diagram of process for volunteer participants

